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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,339	08/31/2001	Edmund K. Waller	05010.0087U1	1418
7590 10/02/2003 NEEDLE & ROSENBERG, P.C. The Candler Building Suite 1200 127 Peachtree Street, N.E. Atlanta, GA 30303-1811			EXAMINER BELYAVSKIY, MICHAEL A	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/945,339

Applicant(s)

WALLER ET AL.

Examiner

Michail A Belyavskiy

Art Unit

1644

--Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

THE REPLY FILED 14 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-6 and 15-20.Claim(s) withdrawn from consideration: 7-14 and 21-58.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-6 and 15 -20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waller (US Patent 5,800,539) in view of Sykes et al. (WO 99/25367) essentially for the same reasons set forth in the previous Office Action, Paper No: 14 mailed 04/09/03

Applicant's arguments, filed 08/14/03 have been fully considered, but have not been found convincing.

Applicant asserts that while Sykes et al., may indicate that the presence of T is desirable and teaches the retention of some T cells, Sykes et al., does not disclosed or suggest whether the retained cells have the ability to proliferate, and it would not be obvious to one of the skill in the art to use fludarabine to result in T cell capable of proliferating. However, Applicant further indicates that as far as Sykes et al., disclosed the T cell may be able to proliferate or may not be able to proliferate at all ( see page 3 of the Applicant's arguments, file 08/14/03).

It appears that applicant and the examiner differ on interpretation the prior art. Also, applicant relies upon an asserted and claimed mechanism of action of fludarabine ( T cells retained ability to proliferate after treatment with fludarabine), but does not appear to distinguish the prior art teaching the same method to achieve the same endpoint. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

It is the examiner position that Sykes et al., teach a method of a myeloreductive non-myeloablative treatment with fludarabine, the same type of treatment as claimed invention. Sykes et al., teach that for successful transplantation of hematopoietic cells from donor to recipient, it is essential that after treatment T cells are not completely depleted, thus so called graft-verses leukemia (GvL) effects of the non-depleted T cells help engraftment of donor hematopoietic cells ( see page 10, lines 17-23, page 11, line 5-25 in particular). Sykes et al., specifically stressed that said treatment should not completely eliminated T cells (page 16, lines 2-11 in particular).

It is clear that both the prior art and applicant administer the same treatment to achieve the same results. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to conclude that this myeloreductive non-myeloablative treatment with fludarabine would produced T cells that retain their ability to proliferate in the recipient. When the prior art method is the same as a method described in the specification, it can be assumed the method will obviously perform the claimed process absent a showing of unobvious property. .

  
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